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REMARKS

Claims 32-39 and 41-47 are now pending for prosecution in this case.

Objections

Claims 34, 36, 45 and 46 are objected to for alleged informalities.

In response, Applicants respectfully submit that these informalities have been corrected and have rendered the objections moot.

The Rejection under 35 U.S.C. § 112, First Paragraph

Claim 35 stands rejected under 35 U.S.C. §112, First Paragraph as allegedly failing to contain a written description of the claimed invention, such that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) has possession of the claimed invention. The Examiner has further recommended precise language that would render the rejection moot.

In response, Applicants have amended Claim 35 to recite the recommended claim language. Support for the amendment appears at least at page 12, lines 13-33.

The Double-Patenting Rejection

Claims 32-39 and 41-47 stand rejected under the judicially-created doctrine of double-patenting over U.S.P. 5,994,511 and U.S.P. 5,622,700.

Specifically, the Examiner has asserted that the '511 patent teaches the same anti-IgE antibodies or IgE binding fragments thereof absent the immunosuppressive agent. Moreover, the '700 patent teaches the immunosuppressive agents of the instant claims in combination with a different antibody. The Examiner then argues that "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 205 U.S.P.Q. 1069, 1072 (CCPA 1980); M.P.E.P. § 2144.06.

In response, Applicants respectfully submit that the Examiner's reliance upon *In re Kerkhoven* and M.P.E.P. § 2144.06 as authority for the rejection is misplaced.

The MPEP section and recited case law describes the concept of art-recognized equivalence for the substitution of components in support of an obviousness rejection.

In *Kerkhoven*, the Court of Customs and Patent Appeals ("CCPA") affirmed a decision of the Board of Appeals and Patent Interference's affirmation of an Examiner's Final Rejection to a method of preparing a spray-dried composition comprising separately spray-drying ionic and non-ionic components, followed by mixing the dried components together. (Incidentally, the CCPA reversed the board on a claim to the simultaneously spray-drying of the ionic and non-ionic components through separate nozzles). The problem that the invention was intending to solve was to create a detergent with excellent flow characteristics, as contemporary detergents containing both ionic and non-ionic (mixed-active) components produced by spray-drying a single slurry possessed poor flow properties.

The most relevant prior art described a process for producing multi-colored detergents by spraying separate slurries through separate nozzles into the same spray-drying tower. The CCPA apparently adopted the Solicitor's reasoning that armed with the knowledge that non mixed-active ingredients do not posses poor flow characteristics, one of ordinary skill would readily understand that the mixed-active components can be dried separately and then mixed. (However, the simultaneous drying and mixing effected by spraying the separate ionic and non-ionic components into the same spray-drying tower was found to be patentable because there was no motivation to use a technique for providing mixed coloration to solve the separate and distinct problem of flow characteristics).

Turning now to the case at hand, the claims in the present application relates to a composition of specific anti-IgE antibodies and IgE-binding fragments in combination with immunosuppressive agents. Thus, the present situation is not akin to that described in M.P.E.P. § 2144.06 and *In re Kerkhoven* where individual components (process steps) are combined to effect a similar result together (excellent flow properties of mixed-active ingredient), as that which they were known already to accomplish individually (excellent flow properties of unmixed-active ingredient).

While similar immunosuppressive agents are indeed disclosed in the '700 patent, there is no suggestion or motivation to combine them with anti-IgE antibodies. Moreover, these immunosuppressive agents are not claimed in combination with the anti-LFA-antibodies. Furthermore, there is no suggestion or motivation in the claims of the recited patent claim to substitute anti-IgE for anti-LFA in a combined composition of antibody and immunosuppressive agent.

Finally, as the Examiner has pointed out, a double-patenting rejection is based on an unjustified or improper timewise extension of the "right to exclude" granted by a patent. The application of the disclosure of the '700 patent, and not the claims contained therein is improper because there is simply no overlap between the presently claimed subject matter and the claims of the '700 patent. Since there is no overlap of the claimed subject matter, there can be no improper extension of patent term.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Applicants believe that this application is now in condition for immediate allowance and respectfully request that the outstanding objections and rejections be withdrawn and this case passed to issue.

The examiner is invited to contact the undersigned at (650) 225-1489 in order to expedite the resolution of any remaining issues.

Respectfully submitted,
GENENTECH, INC.

Date: August 23, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

The title of the application has been amended as follows:

THERAPEUTIC COMPOSITIONS COMPRISING ANTI-IGE ANTIBODIES AND ~~METHOD OF IMPROVING POLYPEPTIDES~~IMMUNOSUPPRESSIVE AGENT

In the claims:

Claims 34-36, 45 and 46 have been amended as follows:

34. (Three times Amended) The composition of Claim 32, wherein the immunosuppressive agent is a glucocorticosteroid.

35. (Three times Amended) The composition of Claim 32, wherein the immunosuppressive agent is selected from the group consisting of: cyclosporin A; an anti-CD3 antibody; an anti-CD4 antibody and an anti-CD4a antibody.

36. (Three times Amended) The composition of Claim 32, wherein the immunosuppressive agent is selected from the group consisting of: a soluble peptide containing an LFA-3 binding domain; streptokinase; TGF-β; streptodornase; deoxyspergualin; rapamycin and a T-cell receptor.

45. (Amended) The composition of Claim 32, wherein the immunosuppressive agent is a cytokine antagonist or a cytokine receptor antagonists.

46. (Twice Amended) The composition of Claim 45, wherein the immunosuppressive agent is an antibody selected from the group consisting of: an anti-interferon-γ antibody, an anti-interferon-β antibody, ~~or~~ an anti-interferon-α antibody; an anti-tumor necrosis factor-α antibody, an anti-tumor necrosis factor-β antibody, an anti-interleukin-2 antibody, an anti-IL-2 receptor antibody and an anti-L3T4 antibody.